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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,962	10/21/2003	Gary Levy	9579-80	3922

1059 7590 03/28/2006

BERESKIN AND PARR  
40 KING STREET WEST  
BOX 401  
TORONTO, ON M5H 3Y2  
CANADA

EXAMINER

BOESEN, AGNIESZKA

ART UNIT PAPER NUMBER

1648

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/688,962

Applicant(s)

LEVY, GARY

Examiner

Agnieszka Boesen

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/21/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/8/2004</u>   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's amendment filed on 10/21/2003 is acknowledged. Claims 19-32 are pending.

#### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 20, 21, 23-30, and 32 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 20, 21, 23-30, and 32. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

- I. Claims 19, 22, and 31, drawn to a method of preventing or reducing immune coagulation associated with fgl-2 expression comprising administering an effective amount of a **gene** inhibitor, wherein the inhibitor inhibits the LF-A1 gene, classified in class 514, subclass 44.
  - II. Claims 19 and 22, drawn to drawn to a method of preventing or reducing immune coagulation associated with fgl-2 expression comprising administering an effective amount of a **protein** inhibitor, wherein the inhibitor inhibits the LF-A1 protein, classified in class 435, subclass 69.1.
1. Inventions I and II are directed to related method of preventing or reducing immune coagulation. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of inhibiting a gene does not overlap with the method of inhibiting the protein and vice versa as evidenced by the distinct structures such as the inhibition of the protein structure requires a protein inhibitor and the inhibition of a gene requires a nucleic acid inhibitor. The gene therapy mode of operation of Group I, which is different from the protein treatment of Group II.

6. Claims 24, 27, 28, and 30 are objected to because of the following informalities: The recitation of "SEQ. ID. NO. 1" is improper; it should be "SEQ ID NO: 1". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 19, and claims 20-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is incomplete because there is no correlation between the method steps and the method recited in the preamble. This rejection also affects claims 20-32.

While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination. The metes and bounds of the claims cannot be determined without method steps that link the inhibition of the LF-1A gene in an animal to the prevention or reduction in immune coagulation associated with fgl2 expression. The claims lack a nexus between the preamble and the method steps.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Michelin Gravelle on March 10, 2006 a provisional election was made with traverse to prosecute the invention of a method to inhibit an LF-A1 gene using an antisense oligonucleotide, claims 19-32. The protein inhibitor of LF-A1 protein, claims 19 and 22, has been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Affirmation of this election must be made by applicant in replying to this Office action.

#### ***Claim Objections***

5. Claim 19-32 are objected to because of the following informalities: the claims recite non-elected subject matter, an LF-A1 protein.

Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is noted that claim 31 states that the inhibitor is an inhibitor of the LF-A1 gene. Since the LF-A1 protein recited in claim 19 is withdrawn from consideration, claim 31 would fail to further limit claim 19 upon cancellation of the non-elected LF-A1 protein. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 19-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The inhibitor of claims 19-21 and 31 is only characterized by the function of inhibiting the LF-A1 gene. There is no structure for the claimed inhibitor and the skilled artisan would be unable to envision an unidentified molecule that is capable of inhibiting an LF-A1 gene to reduce immune coagulation. The specification generally discusses inhibitors as antibodies (see pages 7-10), antisense molecules that include antisense oligonucleotides (see pages 10-13) and other “substances” that inhibit binding of the N-protein from a hepatitis virus. However, the specification does not describe a specific inhibitor that possesses the function required by the claims.

Dependent claims 22, 26, 29, and 32 state that the inhibitor is an antisense oligonucleotide that is complementary to the fgl-2 promoter region, a “portion” of the fgl-2

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promoter, the LF-A1 binding element within the fgl-2 promoter and any sequence complementary to an LF-A1 gene. The specification describes the mouse fgl-2 gene and identifies the LF-A1 binding sequence within the promoter in Figure 2. The specification also teaches that the region within the fgl-2 promoter from -372 to -306 is the site responsive to induction of the N-protein and also identifies -332 to -325 as the LF-A1 binding element region on page 28. However, the claims encompass an antisense oligonucleotide complementing any fgl-2 promoter or portion of the promoter, which is not limited to the mouse fgl-2 sequence described. Applicant has not described fgl-2 sequences from any other organism. Therefore, the applicant does not convey possession of fgl-2 genes from any other animal and does not convey possessions of sequences that would complement these undescribed sequences. There is also no written description for sequences complementing the fgl-2 gene sequence presented in Figure 2. There is also a lack of disclosure for LF-A1 sequence or a sequence that would be complementary thereto.

Claim 23 states that the antisense oligonucleotide comprises at least 8 nucleotides that are complementary to any 8 nucleic acid sequences within fgl-2 promoter region. Claims 24, 25, 27, 28, and 30 recite specific sequences encompassed by SEQ ID NO: 1 that the antisense oligonucleotide complements. However for the reasons discussed above, the disclosure does not convey possession of any antisense sequence for the fgl-2 promoter described in Figure 2 or fgl-2 promoter for any other animal. The specification does not teach a single antisense oligonucleotide of any length that is complementary to any fgl-2 sequence or SEQ ID NO: 1. Nor does the specification teach an antisense oligonucleotide of any length that meets the functional requirement of the claims to inhibit an LF-A1 gene to prevent or reduce immune



coagulation. The only factor present in the claims is a functional limitation for inhibition of LF-A1. There is no identification of any particular structure the inhibitor must possess.

Accordingly, in the absence of sufficient recitation distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus of LF-A1 inhibitors.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*[Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method*

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of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required.

See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

There is no description of an inhibitor that possesses the required function of inhibiting the LF-A1 gene to prevent or reduce immune coagulation. There is no structural description of an antisense oligonucleotide complementing any portion of the mouse fgl-2 promoter, an fgl-2 promoter from another organism or the LF-A1 gene.

Therefore, it is determined that the specification does not convey possession of any inhibitor or antisense oligonucleotide claimed. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such way as to enable one skilled in the art to which it pertains, or with which it is most clearly connected, to make and/or use the invention.

Claim 22, describes the inhibitor as an antisense oligonucleotide that inhibits the LF-A1 gene. The nature of the invention is drawn to inhibiting the association between an fgl-2 promoter and an LF-A1 gene to prevent or reduce immune coagulation. The claim specifies that the sequence of the oligonucleotide comprises a sequence that is complementary to the fgl-2 promoter region or a "portion" of the fgl-2 promoter. The skilled artisan would be unable to make or use the invention claimed because even if application conveyed possession of an

antisense oligonucleotide, the an antisense oligonucleotide does not possess particular structural characteristics that would enable it to inhibit an LF-A1 gene. There are no working examples demonstrating inhibition of an LF-A1 gene with an antisense oligonucleotide complementary to fgl-2 promoter sequence. There is also no guidance provided by the inventor for inhibiting a gene with an antisense oligonucleotide. The lack of guidance and working examples in the disclosure demonstrating how the skilled artisan would be able to practice the invention claimed, it is determined that an undue quantity of experimentation would be required of the skilled artisan to make or use the invention.

As discussed above, the disclosure does not provide adequate written description for any LF-A1 inhibitor or any antisense oligonucleotide that binds to any portion of a fgl-2 promoter region that inhibits association between fgl-2 and LF-A1. Although the specification discloses SEQ ID NO: 1 and the mouse fgl-2 sequence in Figure 2, there is no written description for antisense sequences complimenting these sequences. The disclosure also does not convey possession of other fgl-2 sequences from other organisms or any antisense sequences that would be complementary thereto. However, the scope of the claims encompass inhibiting LF-A1 and fgl-2 association in mice as well as any animal comprising fgl-2.

The skilled artisan would be unable to practice the invention even if the application did convey possession of the antisense oligonucleotide that specifically complemented portions of SEQ ID NO: 1 recited in claims 24, 27, 28, and 30. SEQ ID NO: 1 is derived from a mouse fgl-2 promoter. The skilled artisan would be unable to inhibit immune coagulation in humans with the instant antisense oligonucleotide because the oligo would be unable to bind to the appropriate

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sequence within the human fgl-2 promoter. The sequences encoding the fgl-2 genes are dissimilar. Ding et al., (abstract no: 365, reference no: IDS # 4) teaches that the sequence similarity between fgl-2 and hfgl-2 proteins is over 70% and that these proteins are 90% identical in amino acid sequence, but only at the C-terminal end. Therefore, the specific antisense oligonucleotide sequences recited in claims 24, 27, 28, and 30 would not correlate to the human sequence of fgl-2 because of 30% difference between the residues between the mouse and human fgl-2.

Further the skilled artisan would not be able to inhibit immune coagulation associated with fgl-2 expressed by administering an antisense oligonucleotide. Lonnberg *et al.* (Annals of Medicine. 1996; 28:511-522) reviews the state of the art for antisense oligonucleotide and modifications to these compounds that are used to enhance the bioactivity of the oligos. Lonnberg et al., teach that unmodified oligonucleotides are vulnerable to extra- and intracellular nucleases and have a significantly short biological half-life. Although some chemical additions to antisense oligonucleotide increase resistance to enzymes, modified forms of the oligos exhibit decreased binding affinity and specificity to the target sequence. Lonnberg et al., conclude that while antisense oligonucleotides are attractive chemotherapeutic agents, several significant obstacles, such lack of stability, affinity, specificity and cellular delivery remain to be resolved. Applicant does not provide any guidance to overcome any of the obstacles discussed by Lonnberg et al. There are also no working examples demonstrating the effectiveness of the specific antisense oligonucleotide claimed for inhibiting immune coagulation associated with fgl-2.

The skilled artisan would doubt that inhibition of LF-A1 binding to fgl-2 would prevent or reduce any fgl-2 associated immune coagulation. Although fgl-2 is directly linked to MHV-3

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virus-induced fulminant hepatic failure in mice, fgl-2 is a factor in various diverse disorders, such as cardiovascular disorders, diabetes, gastrointestinal diseases, fetal loss syndrome, and bacterial and viral infections, see Yuwaraj et al., (Genomics. 2001; 71: 330-338). Therefore, administering an antisense oligonucleotide to inhibit binding between LF-A1 and fgl-2 would not prevent or reduce immune coagulation associated with fgl-2 in all of the various disorders. . Yuwaraj et al., teach that the function of human fgl-2 is not clearly defined and the specific factors determining fgl-2 expression in humans are not known. Yuwaraj et al., also teach that is not known whether allelic variants exist in the fgl-2 gene or if the gene represents an inherited molecular determinant in human hepatitis. There is no nexus in the art between human fgl-2 and hepatitis infection.

Even if these concerns were overcome, the skilled artisan would doubt that the instant, undescribed antisense oligonucleotide inhibitors would have the desired effect on the immune coagulation associated with fgl-2 expression in murine hepatitis virus infection. The working examples in the specification teach that the induction of fgl-2 is not always in murine models of hepatitis virus, see pages 24-27, which discuss the inability of MHV-2 to induce transcription of fgl-2. The working examples demonstrate the lack of predictability for fgl-2 expression and its putative role in every type of murine hepatitis. Therefore, the skilled artisan would not conclude that the instant antisense oligonucleotide inhibitor would be effective in hepatitis infection because of the discrepancies observed in the murine viruses and the different functions of fgl-2 in murine hepatitis.

In conclusion, the specification does not describe the claimed inhibitors. The state of the art indicates that any antisense oligonucleotide for specific sequences for specific sequences of

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SEQ ID NO: 1 would not bind to other fgl-2 sequences. Also, there is a lack of working examples and guidance circumventing the concerns discussed by Lonnberg et al., for delivering the antisense oligonucleotide inhibitors to provide stability and resistance to in vivo nucleases as well as permeabilizing the cell membrane in sufficient amounts to specifically block LF-A1 and fgl-2 binding. The skilled artisan would doubt that the instant inhibitor would be effective for reducing immune coagulation associated with fgl-2 because the function of fgl-2 in humans is uncharacterized. The skilled artisan would also doubt that the invention would be effective against murine hepatitis because the working examples indicate that fgl-2 expression is not always present in murine models. For these reasons, it is determined that an undue quantity of experimentation would be required of the skilled artisan to make and /or use the invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 19-23, 25-26, and 29, are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (Journal of Virology. 1997; 71 (12): 9223-9230) and Mizutani et al. (Journal of Veterinary Medical Science. 1994; 56 (2): 211-215, abstract only). The claims are drawn to a method of reducing immune coagulation associated with fgl-2 expression comprising administering an effective amount of an inhibitor, composed of at least 8 nucleotides

complementary to an 8 nucleotide consecutive sequence of the fgl-2 promoter region, to the animal infected with a hepatitis virus, wherein the inhibitor is inhibiting the LF-A1 gene. The inventor has determined that liver factor (LF-A1) is a CIS acting regulatory element found in the fgl-2 promoter region at nucleotides 332-to 325 and it is responsible for fgl-2 induction.

Ding et al. teaches immune coagulation caused by murine hepatitis virus strain 3 (MHV-3) is caused by induction of fgl-2 prothrombinase gene. Ding et al. does not teach reducing immune coagulation with an antisense oligonucleotide that complements the promoter of the fgl-2 gene.

However, Mizutani et al. teaches an antisense oligonucleotide that is directed against the nucleocapsid protein of MHV reduces viral transcription and replication.

One of ordinary skill in the art at the time the invention was made would have been motivated to reduce immune coagulation caused by MHV to prevent fulminant liver failure. The skilled artisan would have been further motivated to use an antisense oligonucleotide to reduce immune coagulation induced by fgl-2 because these substances are known to inhibit the genes they bind to and they are easily synthesized. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for producing the claimed invention because Ding et al. teaches that the induction of fgl-2 RNA transcripts promotes immune coagulation and Mizutani et al. teaches inhibition of viral transcription with an antisense oligonucleotide. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

10. No claims are allowed.

*Notice of Possible Rejoinder*

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the



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product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen, Ph.D. whose telephone number is 571-272-8035. The examiner can normally be reached on M – F (9:00AM – 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*AB*

Agnieszka Boesen, Ph.D.

*March 23, 2003*

*Stacy B. Chen*

Stacy B. Chen  
Patent Examiner  
Art Unit 1648